REMARKS

Claims 2, 12, 17, 23, and 26-28 have been amended. Claims 1-30 are pending in the application. Applicants reserve the right to pursue the original claims and other claims in this and other applications.

Claims 1-10, 12, 17, 23, and 26-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu in view of Yasushi. The rejection is respectfully traversed.

Claim 1 recites particle beam irradiation equipment comprising a "plurality of second scatterers including a second scatterer for smaller irradiation field size ... at a first position ... and another second scatterer for larger irradiation field size ... at a second position upstream of said first position." Chu and Yasushi, alone or in combination, do not teach or suggest these important limitations.

The Office Action improperly combines Chu and Yasushi to allegedly arrive at the claimed invention. The problem sought to be solved by Chu is distinct from the present invention. Chu states "a double-scattering system developed for a certain beam must be modified if any of these beam parameters are changed." Chu at p. 2082. In Chu, the second scatterer is moved as a result of the occluder being moved, and the occluder is moved to compensate for changes of certain beam characteristics. *Id.* Chu's motivation for moving the second scatterer is clearly shown by the statement "[w]hen the energy of the beam is modulated by an absorber and consequently the values of the beam widths are made larger, the occluder assembly may be moved upstream nearer to the first scatterer so that the projected radii at the isocenter are proportionally increased." *Id.* Chu further discloses "[t]his process compensates the parameters in such a way that the resulting dose distribution again exhibits an acceptable deviation from the average." *Id.* Therefore, Chu maintains uniform dose distribution at the isocenter by moving the occluder assembly upstream toward the first scatterer. Consequently Chu must also move the second scatterer as a response to moving the occluder assembly.

In contrast to Chu, the present application discloses multiple second scatterers, placed at multiple positions, each having a distinct thickness. Chu fails to disclose these aspects of the

present invention because the double-scattering method of Chu includes the occluder assembly, making it unnecessary to change the thickness of the second scatterer. Furthermore, Chu does not address the problem of "deviation occur[ing] between an axis along which the ion beam travels and the center position of the second scatterer, [and] dose uniformity ... deteriorat[ing] depending on the deviation to a larger extent as the distance between the first and second scatterers decreases." Application at p. 30 l. 14 – p. 31 l. 15. Chu notes the problem, stating "[t]o ensure the proper workings of a double-scattering system, the beam profile broadened by the first scatterer must have a correct σ at the occluder, and its central ray must be *very precisely aligned* with the axis of the occluder assembly," but does not provide the solution of the present invention. Chu at 2082 (emphasis added).

The Office Action attempts to cure these deficiencies of Chu with Yasushi. Yasushi, however, is not directed to double scattering method irradiation systems; therefore the role of any scatterers disclosed by Yasushi fundamentally differs from those of the present invention. Additionally, Yasushi is cited as teaching "choos[ing] which scatterer to [be] used based upon the degree of scattering desired with the position of the chosen scatterer being further upstream of the direction of travel of the charged particle beam when more scattering is required." Office Action at p. 3. Yasushi, however, merely states that "scattering effect varies depending on not only the material and thickness of the film used in the scatterer device, but also the distance from the diseased part." Yasushi at ¶ 0138. In contrast, claim 1 recites "a second scatterer ... at a first position ... used when said collimator is adapted for a relatively small first irradiation field and another second scatterer for larger irradiation field size ... at a second position upstream of said first position ... used when said collimator is adapted for a larger second irradiation field." This recitation of two specific scatterers, at two relative positions, and used in conjunction with two relatively sized irradiation fields is what enables the dose uniformity that is a significant goal of the present application.

In contrast to the present application's goal, Yasushi's goal is to enable adjustment of the diameter of a spot beam at each position in the diseased part in order to attain uniformity over an irradiation area while simultaneously improving the dose distribution sharpness at the boundary

of the irradiation area. Yasushi at ¶ 0028. Yasushi also discloses the particle beam irradiation equipment comprising a range shifter (7) for shifting the energy of the particle spot beam, and scanning magnets (3a, 3b) for changing the irradiation position of the particle beam so that the energy and position of the particle spot beam is controlled during irradiation on the affected part. The equipment of Yasushi further comprises a scatterer device (9) allowing for the shifting of the diameter of the spot beam into a plurality of sizes. Yasushi at Abstract. Moreover, Yasushi states "this embodiment utilizes the fact that the scattering effect varies depending on not only the material and thickness of the film used in the scatterer device, but also the distance from the diseased part ... [i]n spite of the scatterer devices having the same construction, the beam diameter is enlarged at a larger rate by the scatterer device 19 disposed at a position farther distant from the diseased part." This describes a scattering effect that differs depending on the distance from the diseased part, and a beam diameter that is enlarged at a faster rate as the scatterer device is positioned more upwardly.

Unlike Yasushi, the present application provides irradiation equipment that provides a charged particle beam with a long range in the patient body, but that also has high dose uniformity at any irradiation field size. This application has disclosed and rectified problems of the double scattering method. Primarily, this application recognizes that while the range length is increased as the distance between the second scatterer and the first scatterer decreases, a large distance between the second scatterer and the first scatterer also exacerbates any deviation between the axis along which the ion beam travels and the center position of the second scatterer. Application at p. 30 l. 14 – p. 31 l. 15. Exacerbation of this deviation results in a deterioration of dose uniformity. *Id.* Additionally, the present application discloses that any deviation between an axis along which the ion beam travels and the center position of the second scatterer occurring when a comparatively small irradiation field is formed results in greater deterioration of dose uniformity. *Id.* In contrast, when a comparatively large irradiation field is formed, the deterioration of dose uniformity is less severe. Application at p. 32 l. 1-32. The present application seeks to solve these problems. Application at p. 30 l. 13 – p. 35 l. 10. Accordingly,

Chu and Yasushi are not properly combinable, and even if combinable, do not teach or suggest all of the limitations of claim 1.

Claim 2 recites particle beam irradiation equipment comprising "a second scatterer device including a plurality of second scatterers through which a Gaussian distributed charged particle beam passes." Chu and Yasushi do not teach or suggest these important limitations.

In the present invention, the plural second scatterers pass a Gaussian distributed charged particle beam. Application at p. 11, ll. 8-20. The Gaussian distributed charged particle beam has been spread out into a Gaussian distribution by the first scatterer to produce a uniform dose distribution, thereby providing a beam irradiation of a double scattering method in combination with said first scatterer of the first scatterer device. *Id.*

In Chu, the first and second scatterers are not configured as recited in claim 2. More specifically, Chu discloses a beam delivery system of a double scattering method comprising a first scatterer and a second scatterer, but in the delivery system, an occluding post (FIG. 35) or occluding post and ring (FIG. 36) is disposed between the first and second scatterer. Chu at p. 2081, FIG. 35, 36. Further, Chu describes the "double-scattering beam delivery method" as "us[ing] an occluding post of sufficient thickness to stop the beam particles which is placed in such a way that it blocks the central portion of the Gaussian distribution." Chu at p. 2080. Chu goes on to say that "[p]ast the occluder ... the second scatterer, of an appropriate thickness and placed strategically, diffuses the particles in these two peaks filling the dose void in the middle, and produces at the isocenter a larger flat-dose area." *Id.* Thus, the beam delivery method shown in FIGS. 35 and 36 are of the double-scattering method using the occluding post (FIG. 35) or occluding post and ring (FIG. 36), but does not include "a plurality of second scatterers through which a Gaussian distributed charged particle beam passes" as recited by claim 2.

Independent claims 12, 17, 23, 26, 27, and 28 contain limitations similar to those present in claims 1 and 2, and are allowable for the above reasons, and on their own merits... Claims 3-6 depend from claim 2 and are patentable at least for the reasons mentioned above. Claims 7-10 depend from claim 26 and are patentable at least for the reasons mentioned above. Claim 29

depends from claim 28 and is patentable at least for the reasons mentioned above. Accordingly, the rejection should be withdrawn and the claims allowed.

Claims 11, 15, 16, 21, and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu in view of Yasushi and either Moyers or Hernandez. The rejection is respectfully traversed. Claim 11 depends from claim 26, claims 15 and 16 depend from claim 12, and claims 21 and 22 depend from claim 17 and are patentable over Chu and Yasushi for at least the reasons mentioned above. Moyers and Hernandez fail to cure the deficiencies of Chu and Yasushi discussed above. Accordingly, Applicants respectfully request that the rejection be withdrawn and the claims allowed.

Claims 13, 14, 18-20, 24, 25, and 30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu in view of Yasushi and Huntziger. The rejection is respectfully traversed. Claims 13 and 14 depend from claim 12, claims 18-20 depend from claim 17, claims 24 and 25 depend from claim 23, and claim 30 depends from claim 28, each of these claims is patentable over Chu and Yasushi for at least the reasons mentioned above. Huntziger does not cure the deficiencies of Chu and Yasushi discussed above. Accordingly, Applicants respectfully request that the rejection be withdrawn and the claims allowed.

In view of the above, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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